Drug Pedigree and RFID in the Pharmaceutical Supply Chain: A Recommendation to the FDA

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FDA RFID Workshop
8-9 February 2006, Washington, D.C.

Technology Comments in 7 Minutes (or Less)...Pointing out the Obvious

We are here to talk directly about…

…serialization

…RFID

…pedigree

…adoption and time frame

…indirectly about…

…patient safety

Pointing out the Obvious

Pointing out the Obvious (1)

Serialization, RFID, and Pedigree…

…are distinct concepts

…have technologically different requirements

…**should be separated in regulations and timelines**

Pointing out the Obvious (2)

- **Today, Technology is functionally capable**
  - Existing IT (information technology) can be used to achieve pedigree
  - Authentication mechanisms available and proven
  - Automated identification technologies available and proven
  - RFID technologies available and proven
  - Linear bar code encoding NDC or HIBC in process for items

- **FDA Timelines on Pedigree and RFID are technically feasible.**

Pointing out the Obvious (3)

- **Today, Cost and ROI are high and proven in theory resp.**
  - IT is not deployed to handle pedigree (cost of deployment)
  - RFID costs are high but falling (passive UHF)
  - 2D bar codes available but not presently mandated
  - No serialization scheme has been mandated or agreed by industry

- **Business issues such as system cost and ROI may mean a longer timeline or phased implementation approach.**

- **Serialization scheme must be defined in very near term.**

Some Technical Notes

Serialization

- **Serialization…**
  - …should be used to uniquely identify each item
  - …should be used to uniquely identify each case
  - …should be used to uniquely identify each pallet
  - …should be used to uniquely identify each object

  - …should be a one-time-use number at all levels
  - …should have sufficient capacity to uniquely identify every item for at least 100 years
  - …should allow unique identifiers from multiple namespaces (e.g., DoD UID)
  - …should be secure
  - …may be private
  - …may be “closed out”

RFID

- **RFID…**
  - …is an automated identification technology
  - …is a carrier of information and other functionality
  - …is cost prohibitive for many items (e.g., OTC aspirin 100 tablet)
  - …functionality and frequencies will vary greatly
  - …use will require visual backup
    - …human readable - linear bar code encoding NDC or HIBC
    - …repeated information - 2D bar code encoding unique object identifier
  - …FDA should mandate 2D bar code and recommend RFID
  - …FDA should create congruency between 2D and linear bar code timelines

Pedigree

- **Pedigree…**
  - …is an information authentication mechanism
  - …is independent of any automated identification technology used
  - …is dependent upon unique object identification (serialization) to be completely effective

  - …can be performed on physically encapsulated products (aggregation)
  - …can be maintained either centrally, in a distributed fashion, with the product, or in a combination

Adoption and Timeline Recommendations

Adoption

- **Serialization, RFID, and Pedigree are separable**
- **Timelines and technology are unique and distinct**
- **Existing FDA timelines are technically feasible**
- **Phased regulatory guidelines for different classes of products will encourage early adoption and provide early benefits**
- **Technically feasible to have multi-technology, multi-frequency reading devices at low cost.**

Serialization Timeline

June 2006 - Definition of serialization scheme

Serialization scheme does not need to encode NDC number. These are non-unique and already encoded in linear bar code per 21 CFR 201.25.

Serialization scheme must admit global numbering schemes and existing regional numbering schemes.

RFID (Auto-ID) Timeline

April 26, 2006 - Linear bar codes required by 21 CFR 201.25

Dec 1, 2006 - 2D and linear bar codes achieve congruency

January 2007 - RFID on Case and Pallet of high counterfeit products

January 2008 - RFID on Item of high counterfeit products

January 2009 - RFID on Case and Pallet of all products

January 2010 - RFID on Item of high concern products

Passive UHF RFID today is most suited to case and pallet level tagging.

Passive HF RFID today is most suited to item level tagging.

LF, active, and other RFID today have special purpose suitability.

Pedigree Timeline

Dec 1, 2006 - (A form of) Pedigree is required by PDMA

January 2009 - More detailed regulations, requirements, or recommendations based on state's pedigree experience

Pedigree IT infrastructure is ready to be deployed - growing pains are not an excuse to delay.

Automated identification technologies are available today to assist in the capture of pedigree data.

Pedigree must be implemented at all points in the supply chains by all players.

Thank you!